

Remarks

A. Office Action Summary Sheet:

Regarding the Office Action Summary sheet, form PTOL-326, item "4)" in the section "Disposition of Claims", should indicate claims 1-3, 5-14, 16, and 18-32 are pending in the application. Item "4a)" should indicate that claims 2, 3, 5, 6, 9-12, 14, and 18-20 are withdrawn from consideration.

B. Request for Withdrawal of Finality:

Applicant respectfully requests that the finality of the Office action of January 12, 2004 be withdrawn and the case be reopened because claim 25 has not been addressed. Accordingly, an incomplete Office action has been issued to Applicant. Applicant, therefore, is not aware of the status of claim 25 and cannot respond appropriately with respect to claim 25.

C. Response to Rejections:

1. **Claims 1, 7, 8, 13, 16, 21, 23-24, and 26-32 have been rejected under 35 U.S.C. 102(b) as being anticipated by Cardwell, Patent No. 4,932,947.**

- **Specifically regarding the rejection of claim 1:**

The Examiner has indicated in the rejection that Cardwell teaches a corrugated sheath enclosing a portion of the plunger shaft. However, in Cardwell, the resilient member/stainless steel coil spring 16 (see column 2, lines 4-7; column 3, line 1; Drawings) is not a corrugated sheath and cannot function as a "sheath" (refer to Applicant's specification and drawings which defines the sheath as having continuous inner and outer walls with corrugations, folds, or pleats along the length of the sheath). Additionally, the coil spring 16 of Cardwell does not enclose a portion of the plunger shaft 11 as required by the limitations of the claim, but is positioned exteriorly of the fluid cylinder 12 (syringe barrel) or tube holder 53 and acts as a means of attachment of cylinder 12 to sleeve 18 (see column 3, lines 1-6, column 4, lines 13-15; Drawings). The Examiner has also indicated that Cardwell teaches that the coil spring 16 is attached to a forward face surface of a plunger cap 22 (plunger shaft handle member). However, the coil spring 16 of Cardwell is in no way attached to the forward end face surface of the plunger cap 22 (plunger shaft handle member) of Cardwell (see Drawings). Note from the Cardwell reference that the coil spring 16 is removably

attached to sleeve ears 17 of sleeve 18 (see column 3, lines 6-8). The spring 16 is positioned between ears 17 of sleeve 18 and cylinder ears 21 (syringe barrel handle member) of cylinder 12.

Further, there is no indication in the Cardwell reference that the coil spring 16 is attached to a rearward face surface of the cylinder ears 21.

Also, the Examiner's rejection indicates a corrugated sheath is "attached to the rearward face surface of the syringe barrel." However, claim 1 requires that the corrugated sheath be attached to the rearward face surface of the syringe barrel handle member.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. For these reasons, Applicant submits that Cardwell does not anticipate the claimed subject matter of claim 1. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 7:**

The rejection of claim 7 should be withdrawn for the reasons stated above with respect to claim 1, as claim 7 depends directly from claim 1.

- **Specifically regarding the rejection of claim 8:**

The rejection of claim 8 should be withdrawn because the Cardwell reference does not recite or show a rear terminus of a corrugated sheath that is *molded* to the plunger shaft handle member, as claimed by Applicant. The coil spring 16 of Cardwell is not a corrugated sheath. Additionally, the coil spring 16 of Cardwell is in no way at all associated with the plunger cap 22 and is not molded to plunger cap 22 (plunger shaft handle member). In fact, the Cardwell reference teaches an apparatus that can be assembled and disassembled as needed (see column 2, lines 46-48; column 1, lines 38-40). At column 3, lines 2-5, Cardwell discloses "...*relaxed resilient member 16 is positioned exteriorly of fluid cylinder 12 allowing for easy assembly, maintenance and disassembly of syringe apparatus 10...*" The limitation of claim 8 describes the type of structural attachment present or existing between the corrugated sheath and the plunger shaft handle member. Applicant's corrugated sheath is molded to the plunger shaft handle member and cannot be disassembled – nor does it require user assembly, as does the Cardwell syringe apparatus. The Cardwell reference does not disclose a

corrugated sheath, nor does it disclose a sheath *molded* to the plunger shaft handle member. In fact, Applicant's claimed molded attachment in the Cardwell apparatus would not permit assembly and disassembly of the Cardwell apparatus as Cardwell desires.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Cardwell reference does not anticipate the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn because the Cardwell reference does not teach a corrugated sheath. Note that the coil spring 16 of Cardwell cannot and does not function as a sheath. The Examiner's rejection does not indicate how the limitation of claim 13 is being met. Because the Cardwell reference is deficient for the reasons advanced above, the Cardwell reference does not anticipate the limitations of claim 13. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 16:**

The rejection of claim 16 should be withdrawn for the reasons stated above with respect to claim 1, as claim 16 depends directly from claim 1.

• **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn because the Cardwell reference does not teach a corrugated sheath. Note that the coil spring 16 of Cardwell cannot and does not function as a sheath. The Examiner's rejection does not indicate how the limitation of claim 21 is being met. Because the Cardwell reference is deficient for the reasons advanced above, the Cardwell reference does not anticipate the limitations of claim 21. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Cardwell reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. As previously indicated, Cardwell does not disclose a corrugated sheath. Cardwell teaches that *"It is still another objective of the present invention to provide a syringe apparatus which includes a cylindrical transparent fluid container and a transparent sleeve which receives the fluid container whereby the amount of fluid can be easily, visually monitored."* (see column 1, lines 33-37; abstract). The *"...fluid cylinder 12 is formed from an inexpensive, substantially transparent synthetic polymer..."* (see column 2, lines 66-68). Cardwell further teaches at column 3, lines 11-14 that *"...fluid 19... can be seen through transparent sleeve 18 and transparent fluid cylinder 12..."* It is unclear to Applicant how the claim limitations are met by the Cardwell reference and what teaching in the reference that the Examiner is relying on to meet these limitations. Cardwell desires a transparent fluid cylinder 12, is silent regarding color or tinting of the plunger shaft, and fails to teach a corrugated sheath. The Examiner's rejection does not indicate how the limitations of claim 23 are being met. The Examiner is requested to communicate the portions of the reference being relied upon. The Cardwell reference clearly desires transparency and does not disclose a colored or tinted syringe barrel 12, plunger shaft 11, and does not teach a corrugated sheath. These are clear structural differences between the cited art and Applicant's claim.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. Because the Cardwell reference is deficient for the reasons advanced above, the Cardwell reference does not anticipate the limitations of claim 23. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 24:**

The limitation of Applicant's claim 24 recites, *"...said syringe is provided with a removable closure cap."* The rejection of claim 24 should be withdrawn because the reference does not recite that the syringe is provided with a removable closure cap, as claimed by Applicant. The purpose of the closure cap in Applicant's claimed invention is for mating with and closing the forward end opening of the syringe barrel so as to

maintain sterility of the inner walls of the syringe barrel and to retain materials in the syringe barrel cavity. It is unclear how the Cardwell reference meets the limitations of claim 24. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Cardwell reference does not anticipate the limitations of claim 24. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 26:**

The Examiner's rejection of claim 26 does not indicate what in the Cardwell reference is being relied upon to teach a brace means. In any event, the brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. This is a clear structural difference between Applicant's claimed subject matter and the Cardwell reference and the Examiner is requested to withdraw this rejection. Further, the rejection of claim 26 should be withdrawn for the reasons stated above with respect to claim 1, as claim 26 depends directly from claim 1.

- **Specifically regarding the rejection of claim 27:**

The rejection of claim 27 should be withdrawn for the reasons stated above with respect to claim 1, as claim 27 depends directly from claim 1.

- **Specifically regarding the rejection of claim 28:**

The rejection of claim 28 should be withdrawn for the reasons stated above with respect to claim 1, as claim 28 depends directly from claim 1.

- **Specifically regarding the rejection of claim 29:**

The rejection of claim 29 should be withdrawn because the Cardwell reference does not recite or show a syringe having a corrugated sheath that does not automatically recoil after being lengthened or compressed. The Cardwell reference actually teaches the opposite of Applicant's claimed limitation. Specifically, Cardwell discusses at column 1, lines 62-64 that "*The resilient member automatically retracts*

the fluid cylinder and hypodermic needle..." At column 3, lines 23-28, Cardwell discloses that "...needle 14 is automatically withdrawn and retracts into sleeve 18 upon relaxation of resilient member 16..." The resilient member 16 of Cardwell used in Applicant's invention would make Applicant's syringe non-functional due to its automatic recoil capability. Further, the resilient member or coil spring 16 of Cardwell is not a sheath and does not have the proper connectivity and functionality as Applicant's corrugated sheath. It is unclear how the claimed limitations are met by the Cardwell reference, and what teaching in the reference that the Examiner is relying on to meet the limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Examiner should communicate the portions of the reference being relied upon. The Cardwell reference does not anticipate the limitations of claim 29. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 30:*

The rejection of claim 30 should be withdrawn because the Cardwell reference does not recite a corrugated sheath enclosing the length of the plunger existing between the rearward end face surface of said syringe barrel handle member and the forward face of the plunger shaft handle member, as claimed by Applicant. Regarding the attachment of the corrugated sheath to the rear face surface of the syringe barrel handle member, the Examiner will note in Cardwell that the resilient member or stainless steel coil spring 16 (see column 2, lines 4-7; column 3, line 1; Drawings) is not a corrugated sheath and does not and cannot function as a sheath. Additionally, the coil spring 16 of Cardwell does not enclose the length of the plunger 11 existing between the rearward end face surface of the cylinder ears 21 (syringe barrel handle member) and the forward face of the plunger cap 22 (plunger shaft handle member) (see Drawings), as required by Applicant's claims.

The Examiner has also indicated that Cardwell teaches that the coil spring 16 is attached to the forward face surface of the plunger cap 22. However, the coil spring of Cardwell is in no way associated at all with the plunger shaft 11 or plunger cap 22 (plunger shaft handle member) of Cardwell. Note from the Cardwell reference that the coil spring 16 is removably attached to sleeve ears 17 of sleeve 18 (see column 3, lines 6-8). Note that sleeve 18 is not a syringe barrel. The spring 16 is positioned between

ears 17 of sleeve 18 and cylinder ears 21 (syringe barrel handle member) of cylinder 12 (syringe barrel). Further, there is no indication in the Cardwell reference that the spring 16 is attached to a rearward face surface of the cylinder ears 21.

Also, the Examiner's rejection indicates the corrugated sheath is "attached to the rearward face surface of the syringe barrel." (see rejection). However, claim 1 requires that the corrugated sheath be attached to the rearward face surface of the syringe barrel handle member.

The Cardwell reference does not meet the limitations of claim 30. These are clear and patentable structural distinctions between Applicant's claimed invention and the Cardwell reference. It is unclear how the claimed limitations are met by the Cardwell reference, and what teaching in the reference the Examiner is relying on to meet these limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Cardwell reference does not anticipate the limitations of claim 30. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

• Specifically regarding the rejection of claim 31:

The rejection of claim 31 should be withdrawn because the Cardwell reference does not teach that each successive portion of the plunger shaft that exits a rearward end opening of the syringe barrel is enclosed and encircled by a corrugated sheath. Note also that Cardwell fails to teach a corrugated sheath. The coil spring 16 is not a corrugated sheath and cannot perform the functions required by Applicant's claim. That is, Cardwell's coil spring 16 does not enclose and encircle each successive portion of the plunger shaft 11 as it exits the rearward end opening of cylinder 12 (syringe barrel). In fact, the coil spring 16 of Cardwell is in no way associated at all with the plunger shaft 11 or plunger cap 22 of Cardwell.

The Cardwell reference further does not teach that each successive portion of said plunger shaft that exits a corrugated sheath passes through the syringe rearward end opening. Again, the coil spring 16 in the Cardwell reference is not a corrugated sheath and cannot perform the functions required by Applicant's claim. That is, the Cardwell reference does not teach that each successive portion of the plunger shaft 11 exits a corrugated sheath and passes through a rearward end opening of the cylinder 12.

In fact, the coil spring 16 of Cardwell is in no way associated at all with the plunger shaft 11 or rearward end opening of cylinder 12 of Cardwell.

These are clear and patentable structural and functional distinctions between Applicant's claimed invention and the Cardwell reference. It is unclear how the claimed limitations are met by the Cardwell reference, and what teaching in the reference that the Examiner is relying on to meet these limitations. The Examiner is requested to communicate the portions of the reference being relied upon. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Cardwell reference does not anticipate the limitations of claim 31. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Cardwell and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 32:**

The rejection of claim 32 should be withdrawn for the reasons stated above with respect to claim 1, as claim 32 depends directly from claim 1.

2. Claims 1, 7, 8, 13, 16, 21-24, and 26-32 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tomkiel, U.S. Patent No. 4,927,416, and further in view of Rupp, U.S. Patent No. 5,419,773, or Haworth, U.S. Patent No. 5,219,338.

- **Specifically regarding the rejection of claim 1:**

The Examiner has indicated in the rejection that Tomkiel teaches a corrugated sheath enclosing a portion of the plunger shaft. However, the bellows member 22 does not enclose a portion of the plunger shaft 19 as required by the limitations of the claim, but is positioned exteriorly of the syringe barrel 15 and functions as a stop to keep an attached sheath from separating from the assembly (see column 4, lines 38-4; Drawings). It is further noted that plunger 19 is only visible in Figures 1-3 and 5-7 and there is no indication of bellows 22 enclosing a portion of the plunger 19. Applicant's claim requires this limitation to be present in the reference.

The Examiner has also indicated that Tomkiel teaches that the bellows 22 is attached to a forward face surface of a finger flange 20 (plunger shaft handle member) and a rearward face surface of the finger flange 29 (syringe barrel handle member).

However, the bellows 22 of Tomkiel is not attached to the forward face surface of the finger flange 20 (plunger shaft handle member). Note from the Tomkiel reference that the bellows 22 is attached to portion 21 and holder member 23 (see column 3, line 68 through column 4, line 2). The bellows 22 exists between the members 21 and 23 (see column 4, lines 6-9). Therefore, the Tomkiel reference teaches a bellows 22 that is forward of the finger flange 29. Accordingly, the Tomkiel reference does not teach that the bellows 22 is attached to a rearward face surface of the finger flange 29 (syringe barrel handle member) or to the forward face surface of the finger flange 20 (plunger shaft handle member), as required by claim 1.

The Examiner's rejection also indicates bellows 22 is "attached to the rearward face surface of the syringe barrel." However, claim 1 requires that the corrugated sheath be attached to the rearward face surface of the syringe barrel handle member.

The references to Haworth and Rupp, although cited to make obvious the inclusion of a piston in the Tomkiel reference, do not overcome the deficiencies addressed above.

For the reasons set forth, Applicant submits that the teachings of Tomkiel, Rupp, or Haworth alone or in combination fail to teach or make obvious the claimed subject matter of claim 1. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of the combined references and is requested to withdraw this rejection.

It is noted that the Tomkiel, Rupp, and Haworth references are concerned with providing automatically recovering needle covers for preventing needle sticks to the user or to others who may come in contact with the exposed needle. The Applicant's invention is not concerned with providing a cover for contaminated needles, but rather for providing a corrugated sheath for a plunger shaft and syringe barrel rearward end opening of a syringe.

• **Specifically regarding the rejection of claim 7:**

The rejection of claim 7 should be withdrawn for the reasons stated above with respect to claim 1, as claim 7 depends directly from claim 1.

• **Specifically regarding the rejection of claim 8:**

The rejection of claim 8 should be withdrawn because the references to Tomkiel, Haworth, and Rupp do not recite or show the rear terminus of a corrugated sheath that

is *molded* to the plunger shaft handle member, as claimed by Applicant. The bellows 22 of Tomkiel is not, in any way, at all associated with the plunger cap 20 of Tomkiel. In fact, the Tomkiel reference teaches an apparatus that can be assembled by the user (see column 2, lines 30-32 and 40-42; column 4, lines 15-18). The limitations of Applicant's claim 8 describe the type of structural attachment present or existing between the rear terminus of the corrugated sheath and the forward face surface of the plunger shaft handle member. The Tomkiel, Haworth, and Rupp references do not disclose a corrugated sheath *molded* to a plunger shaft handle member. In fact, Applicant's claimed molded attachment used in the Tomkiel apparatus would not permit assembly of the Tomkiel apparatus as Tomkiel desires. It is also noted that Applicant's syringe is a single unitary structure that is not assembled or disassembled by the user.

For the reasons set forth, Applicant submits that the teachings of Tomkiel, Rupp, or Haworth alone or in combination fail to teach or make obvious the claimed subject matter of claim 8. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of the combined references and is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- **Specifically regarding the rejection of claim 16:**

The rejection of claim 16 should be withdrawn for the reasons stated above with respect to claim 1, as claim 16 depends directly from claim 1.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn for the reasons stated above with respect to claim 1, as claim 21 depends directly from claim 1.

- **Specifically regarding the rejection of claim 22:**

The rejection of claim 22 should be withdrawn for the reasons stated above with respect to claim 1, as claim 22 depends directly from claim 1.

• **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Tomkiel, Rupp, and Haworth references do not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by the references cited and what teachings in the references the Examiner is relying on to meet the limitations. The Tomkiel, Rupp, and Haworth references do not disclose a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted. This is a clear structural difference between the cited art and Applicant's claim.

Because the Tomkiel, Rupp, and Haworth references, alone or in combination, are deficient for the reasons advanced above, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Tomkiel, Rupp, and Haworth either alone or in combination and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 24:**

The limitation of Applicant's claim 24 recites, "...*said syringe is provided with a removable closure cap.*" The rejection of claim 24 should be withdrawn because the references cited do not recite that the syringe is provided with a removable closure cap, as claimed by Applicant. The purpose of the closure cap in Applicant's claimed invention is for mating with and closing the forward end opening of the syringe barrel so as to maintain sterility of the inner walls of the syringe barrel and to retain materials in the syringe barrel. It is unclear how the Tomkiel, Rupp, or Haworth references alone or in combination meet the limitations of claim 24. The Examiner is requested to communicate the portions of the references being relied upon. The cited references do not teach or suggest the limitations of claim 24.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Tomkiel, Rupp, or Haworth, alone or in combination, and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Tomkiel, Rupp, and Haworth references do not recite a brace means, as claimed by Applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn

position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. This is a clear structural difference between Applicant's claimed subject matter and the cited references. It is unclear how the claimed limitations are met by the references, and what teaching in the references the Examiner is relying on to meet the limitation. The Examiner is requested to communicate the portions of the references being relied upon.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Tomkiel, Rupp, or Haworth either alone or in combination and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 27:**

The rejection of claim 27 should be withdrawn for the reasons stated above with respect to claim 1, as claim 27 depends directly from claim 1.

• **Specifically regarding the rejection of claim 28:**

The rejection of claim 28 should be withdrawn for the reasons stated above with respect to claim 1, as claim 28 depends directly from claim 1.

• **Specifically regarding the rejection of claim 29:**

The rejection of claim 29 should be withdrawn because the Tomkiel reference does not recite or show a syringe having a corrugated sheath that does not automatically recoil after being lengthened or compressed. The Tomkiel reference actually teaches the opposite of Applicant's claimed limitation. Specifically, Tomkiel discusses at column 2, lines 56-58 that "*A spring holds the sheath in an extended position upon release of the latch and movement of the sheath to the extended position.*" At column 4, lines 10-14, Tomkiel discloses that "*When latch lugs 24 are released from the notches 28, the sheath and holder member may move apart axially but remain joined together by the bellows member 22, which is extended to accommodate such movement (FIG. 3).*" The bellows 22 of the Tomkiel reference used in Applicant's invention would make Applicant's syringe non-functional due to its automatic recoil capability. It is the desire of Tomkiel to provide automatic recoil action to the bellows member 22. Further, the bellows 22 does not have the proper connectivity and functionality as Applicant's corrugated sheath. Haworth also teaches

the opposite of Applicant's claim limitations. The Haworth reference discloses at column 1, line 63 through column 2, line 3 that "...the sheath is retracted manually to expose the needle...and...the sheath immediately and automatically extends to recover the needle..." Rupp also teaches the opposite of Applicant's claimed limitations. The Rupp reference discloses at column 4, lines 35-41 that "*When lever 168 is pulled back, the corrugated-like tubing 160 folds back...When the lever 168 is released the corrugated tubing 160 springs back...*" and at column 5, lines 8-23 that "*Additional pressure on the levers 226 and 228 causes the corrugated-like tubing 224 to fold back...When the levers 226 and 228 are released, the assembly automatically reseals...*" Further, neither the Haworth or Rupp references disclose the proper connectivity and functionality as Applicant's corrugated sheath. It is unclear how the claimed limitations are met by the cited references, and what teachings in the references that the Examiner is relying on to meet the limitations. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of the cited references and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 30:**

The rejection of claim 30 should be withdrawn because the Tomkiel, Rupp, and Haworth references do not recite a corrugated sheath enclosing the length of the plunger existing between the rearward end face surface of said syringe barrel handle member and the forward face of the plunger shaft handle member, as claimed by Applicant. Regarding the attachment of the corrugated sheath to the rear face surface of the syringe barrel handle member, the Examiner will note that the bellows 22 of Tomkiel does not enclose the length of the plunger existing between the rearward end face surface of the finger flange 29 (syringe barrel handle member) and the forward face of the finger flange 20 (plunger handle member). The Examiner has also indicated that Tomkiel teaches that the bellows 22 is attached to the forward face surface of the finger flange 20 (plunger shaft handle member). However, the bellows 22 of the Tomkiel reference is in no way associated at all with the plunger 19 or finger flange 20 of Tomkiel. Note that the bellows 22 remains forward of the finger flange 29 in Tomkiel and is actually attached to member 23. Additionally, both the Rupp and Haworth references fail to meet this limitation as previously described and are structurally and functionally different from Applicant's invention.

The Examiner's rejection indicates the corrugated sheath is "attached to the rearward face surface of the syringe barrel." However, claim 1 requires that the corrugated sheath be attached to the rearward face surface of the syringe barrel handle member.

The combination of Tomkiel with Rupp, or Haworth does not meet the limitations of claim 30. The differences are clear and patentable structural distinctions between Applicant's claimed invention and the cited references. It is unclear how the claimed limitations are met by the Tomkiel, Rupp, or Haworth references, either alone or in combination, and what teaching in the references the Examiner is relying on to meet the limitations. The cited references do not teach or make obvious the limitations of claim 30. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that taught by the cited references and the Examiner is requested to withdraw this rejection.

• Specifically regarding the rejection of claim 31:

The rejection of claim 31 should be withdrawn because the Tomkiel, Rupp, and Haworth references do not teach that each successive portion of the plunger shaft that exits a rearward end opening of a syringe barrel is enclosed and encircled by a corrugated sheath. The bellows 22 of Tomkiel does not have the claimed connectivity and cannot perform the functions required by Applicant's claim. The bellows 22 of Tomkiel does not enclose and encircle any portion of the plunger shaft 19 as it exits the rearward end opening of the syringe barrel 15. In fact, the bellows 22 of Tomkiel is in no way associated at all with the rearward end opening, plunger shaft 19, or finger flange 20, of Tomkiel. Also, the Rupp and Haworth references do not teach a corrugated sheath associated with a rearward end opening, syringe barrel handle member, or plunger shaft handle member.

The Tomkiel, Rupp, and Haworth references further do not teach that each successive portion of said plunger shaft that exits a corrugated sheath passes through said rearward end opening. Again, the bellows 22 of the Tomkiel reference does not have the claimed connectivity and cannot perform the functions required by Applicant's claim. That is, the reference of Tomkiel does not teach that each successive portion of the plunger shaft that exits the corrugated sheath passes through the rearward end opening of the syringe barrel. In fact, the bellows 22 of Tomkiel is in

no way associated at all with the plunger shaft 19, or finger flange 20, or rearward end opening of the Tomkiel syringe.

Also, the Rupp and Haworth references do not teach a corrugated sheath wherein each successive portion of the plunger shaft that exits a corrugated sheath passes through said rearward end opening of said syringe barrel.

These are clear and patentable structural and functional distinctions between Applicant's claimed invention and the cited references. It is unclear to Applicant how the claimed limitations are met by the cited references, and what teaching in the references that the Examiner is relying on to meet the limitations. The Examiner is requested to communicate the portions of the references being relied upon. The Tomkiel, Rupp, and Haworth references do not teach or make obvious the limitations of claim 31. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of the cited references and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 32:**

The rejection of claim 32 should be withdrawn for the reasons stated above with respect to claim 1, as claim 32 depends directly from claim 1.

3. Claims 1, 7, 8, 13, 16, 21-24, 26-27, and 29-32 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn, III et al., Patent No. 5,817,047.

- **Specifically regarding the rejection of claim 1:**

Initially, it is noted that Osborn, III et al. is non-analogous art. The claimed syringe of the instant invention has specific structural limitations and performs specific functions, as defined by the specification and not disclosed by Osborn, III et al. Osborn, III et al. is drawn to a *combination tampon and tampon inserter* and not to a syringe. Applicant's invention is not drawn to tampons and devices used to dispense and insert tampons. The syringe of the instant invention is not used for holding or inserting tampons. Applicant's invention is drawn to a syringe. Applicant's claimed syringe is not used to hold, insert or dispense tampons. Applicant's specification clearly defines how the structures of the syringe function. A person of ordinary skill in the art would not attempt to use tampon inserters to inject or draw sterile solutions.

The instant syringe is not intended as a holder, inserter, or dispenser of tampons. Further, the instant syringe does not have the structure that would lend it to dispense tampons. It is also noted that the Osborn, III et al. reference makes no mention of the term *syringe*. Osborn, III et al. do not equate tampon inserters to syringes. The structure disclosed and claimed by Osborn, III et al. is structurally and functionally different from Applicant's disclosed structure and claims. These are clear structural and functional differences between the Osborn, III et al. reference and Applicant's claimed invention.

Note that Applicant's claim 1 recites that the plunger shaft has an attached piston, wherein said attached piston is capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston. The examiner rejected the limitations of claim 1 as being taught by Osborn, III et al. Osborn, III et al. do not disclose an *attached* piston. The Examiner's response to this argument in the Final Office Action of September 10, 2003 indicated that the tapered portion of the plunger 30 was being relied upon as meeting the limitation of an attached piston. The tapered portion of the plunger 30 of the Osborn, III et al. reference is not a piston, but is actually a continuation of the plunger 30. The plunger shaft and piston claimed by Applicant are different parts, which are attached together. The tapered portion of plunger 30 in the Osborn III, et al. reference is not an attachment to the plunger 30, *but is plunger 30*. This is a clear structural difference between the Osborn, III et al. reference and Applicant's claim. The piston of Applicant's invention performs a specific function as claimed. The piston claimed by Applicant is not disclosed in the Osborn, III et al. reference. Accordingly, the tampon dispenser of Osborn, III et al. is unable to function as the syringe claimed by Applicant. Further, the tapered portion of the plunger 30 taught by Osborn, III et al. is not capable of functioning as a piston in a syringe, as claimed by Applicant.

Also, Osborn, III et al. do not disclose a plunger shaft having an attached piston capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston, as recited in claim 1. In fact, the Osborn, III et al. reference does not show or recite that the tapered portion of the plunger 30 contacts and forms a tight seal with the walls of the cylinder 50. Advancement of the plunger 30 in the Osborn, III et al. reference cannot be

considered to produce or maintain a tight seal with the length of the cylinder 50. It is noted that the reference does not disclose that withdrawal of the plunger 30 is possible – it certainly is not warranted. It is noted that the tampon positioned in the cylinder 50 of the tampon dispenser impedes advancement of the plunger 30 until the forward end of the cylinder 50 is ruptured. Applicant's syringe does not rupture during advancement of the plunger shaft, nor does it contain and dispense tampons. Thus, the tapered portion of plunger 30 does not contact and slidably engage and maintain a tight seal with the cylinder 50 of the tampon dispenser during advancement or withdrawal of the plunger 30. The instant invention, however, claims an attached piston that *contacts* and slidably engages and maintains a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and piston.

Additionally, the Osborn, III et al. reference does not recite a corrugated sheath attached to a rearward end face surface of said syringe barrel handle member, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 and not to gripping means 60. Note that the limitations of Applicant's claim 1 require that the corrugated sheath be attached to a rearward end face surface of said syringe barrel handle member; the handle member is, in turn, permanently attached to the rearward end terminus of the syringe barrel. However, the Osborn, III et al. reference does not teach a syringe barrel handle member attached to the rear terminus of the syringe barrel or a corrugated sheath attached to a rearward end face surface of the syringe barrel handle member. These are clear structural differences between Applicant's claimed invention and the Osborn, III et al. reference.

The Examiner stated in the rejection that Osborn, III et al. do not teach, *"the corrugated sheath attached to the rearward face surface of the syringe barrel handle member."* In response, it is first noted that Osborn, III et al. do not teach a syringe and refers to article 10 throughout the reference as a combination tampon and inserter.

The Examiner indicates *"At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have attached the bellows to the rearward face surface of the syringe barrel handle member..."* In response, the Examiner has not shown a syringe barrel handle member permanently attached to the *rear terminus* of the hollow syringe barrel and a corrugated sheath attached to the syringe barrel handle member. The connectivity of

Applicant's syringe provides a syringe barrel handle member molded to the rear terminus of the syringe barrel and a corrugated sheath attached to the rearward face surface of the syringe barrel handle member. Because in Applicant's invention the syringe barrel handle member is molded to the rear terminus of the syringe barrel, the rear terminus of the syringe barrel is *not exposed and not available* for attachment of a corrugated sheath. Thus, the corrugated sheath in Applicant's invention is attached to the rearward face surface of the syringe barrel handle member. The tampon dispenser/insertor of Osborn, III et al. does not have this connectivity. Modification of Osborn, III et al. by attachment of the bellows 100 to the gripping means 60, as suggested by the Examiner, *still does not suggest Applicant's claimed invention because gripping means 60 is not attached to the rearward end terminus of cylinder 50*. Further, the Osborn III, et al. reference specifically recites the connectivity between bellows 100 and cylinder 50. There is no suggestion in the Osborn III, et al. reference that this connectivity is open to modification. Such a suggestion broadens the scope of the Osborn III, et al. patent to include subject matter not taught by Osborn III, et al. It must be shown that the prior art could be modified and there exists a suggestion of the desirability or motivation for making the modification. Osborn, III et al. does not provide this motivation. Nor, does the scope of the Osborn, III et al. patent lend itself to modification. Osborn, III et al. is specific in the connectivity of the tampon dispenser. Therefore, it would not have been obvious to have modified the Osborn III, et al. reference as suggested by the Examiner. The Examiner further indicates the design choice to be obvious *"...because Applicant has not disclosed that attached to the rearward face surface of the syringe barrel handle member proves an advantage, is used for a particular purpose, or solves a stated problem."* In response, there is no requirement that an invention produce an advantage to be patentable – it need only be non-obvious.

The Examiner further indicates in the obvious statement that *"One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the bellows attached to the shaft instead of attached to the rearward face surface of the syringe barrel handle member because they perform the same function."* In response, it is unclear to Applicant why the Examiner is modifying Applicant's invention to show that it would have performed equally well with the corrugated sheath attached to the shaft member. Why is there a suggestion that Applicant's invention be modified? It is further unclear to Applicant why the

Examiner would modify Applicant's invention to attach the bellows to the shaft member.

Additionally, the Examiner has made an obvious statement based on what Applicant has not disclosed and states "*Therefore it would have been an obvious matter of design choice to modify Osborn to obtain the invention specified in the claims.*" However, such reasoning as a basis of obviousness looks to Applicant's specification and claimed subject matter to reject Applicant's claims. Further, a statement that a difference between the prior art and the claimed subject matter would have been "an obvious matter of design choice" is, by itself, merely a conclusion and does not communicate the supporting rationale. None of the references cited meets the claimed limitation of attachment of the corrugated sheath to the rearward face surface of the syringe barrel handle member. One cannot arbitrarily modify references to meet the limitations of a claim.

For these reasons, Applicant submits that the Osborn, III et al. reference fails to suggest or make obvious the claimed subject matter of claim 1. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 7:**

The rejection of claim 7 should be withdrawn because the Osborn, III et al. reference does not recite or show that the plunger shaft handle member is *molded* to the rear terminus of the plunger shaft, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 6, lines 33-36, with reference to Figures 1-3, that a seal 90 is located at the rear end of the plunger 30. The seal 90 is separate from the gripping means 70. Note that the gripping means 70 is located on the longitudinal periphery of the plunger 30 and not at the rearward end terminus of the plunger 30. The periphery of the plunger 30 is not the same surface as the rearward end terminus surface. It should be noted that even Osborn, III et al. teach this fact when Osborn, III et al. indicate that seal 90 is located at the rear end of the plunger 30. This is also apparent from the drawings because the hatch marks for the gripping means 70 are not present at the rear terminus of the plunger 30. Note that seal 90 could not be located at the rearward end terminus of the plunger 30, as indicated by Osborn, III et al., if the gripping means 70 were located there. The limitation of Applicant's claim 7 requires that the plunger shaft handle member be located at the rear face terminus of the

plunger shaft -- not located on the longitudinal periphery, as in the Osborn, III et al. reference. This is a clear structural difference between the Osborn, III et al. reference and Applicant's claimed invention. This argument was presented in the response filed July 7, 2003 by Applicant following the First Office Action and in the response filed November 21, 2003, but has not been addressed by the Examiner.

Further, the reference does not teach that the plunger shaft handle member is *molded* to the rear face terminus of the plunger shaft. The Osborn, III et al. reference makes no attempt to discuss the type of attachment, if any, between the plunger shaft handle member and the plunger shaft. The claim describes the type of attachment present or existing between the plunger shaft handle member and the rear face terminus of the plunger shaft. The Osborn, III et al. reference fails to teach or make obvious the limitations of claim 7. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 8:*

The rejection of claim 8 should be withdrawn because the Osborn, III et al. reference does not recite or show the rearward terminus of the corrugated sheath is *molded* to the forward face of the plunger shaft handle member, as claimed by Applicant. The limitation of claim 8 describes the type of structural attachment present or existing between the corrugated sheath and the plunger shaft handle member. The Osborn, III et al. reference is silent and makes no attempt to discuss the type of attachment relationship between the bellows 100 and the gripping means 70 or plunger 30, or even if an attachment is present. One cannot conclude from the drawings that an attachment exists between bellows 100 and gripping means 70 or between the bellows 100 and the plunger 30. To meet the limitation of claim 8, Osborn, III et al. must recite attachment between the forward face surface of gripping means 70 to the bellows 100. The reference must recite the claimed limitation -- it cannot be assumed to be present. Accordingly, it cannot be determined precisely what section of the plunger shaft the bellows 100 is enclosing in Osborn, III et al.

The reference must recite the claimed limitation -- it cannot be assumed to be present. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action and in the response filed November 21, 2003 but has not been addressed by the Examiner.

The Osborn, III et al. reference fails to teach or make obvious the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- **Specifically regarding the rejection of claim 16:**

The rejection of claim 16 should be withdrawn because the Osborn, III et al. reference does not recite that the syringe barrel handle member is *molded* to or *formed* on the rearward end terminus of a syringe barrel, as claimed. The limitation of claim 16 describes the type of structural attachment present or existing between the syringe barrel rearward end terminus and the syringe barrel handle member. In fact, the Osborn, III et al. reference recites only the presence of a gripping means 60 and a tampon dispenser. The gripping means 60 is located on the longitudinal periphery of the tampon-dispensing cylinder 50. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 – not to gripping means 60. Accordingly, attachment of bellows 100 to cylinder 50 would not be possible if gripping means 60 were attached to the terminus of the cylinder 50. The gripping means 60 in the Osborn, III et al. reference is located on the longitudinal periphery of the cylinder 50 and not at the rearward terminus of cylinder 50. This is also apparent from the drawings because the hatch marks for the gripping means 60 are not present at the terminus of the cylinder 50. The limitation of Applicant's claim requires that the syringe barrel handle member be molded or formed on the rearward end terminus of the syringe barrel. Neither the reference nor the Drawings of Osborn, III et al. recite or show a syringe barrel handle member molded to or formed on the rearward end terminus of a syringe barrel. As stated previously, Osborn, III et al. fail to teach a syringe. This is a clear structural difference between the cited art and Applicant's claim.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn for the reasons stated above with respect to claim 1, as claim 21 depends directly from claim 1.

- **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Osborn, III et al. reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by the Osborn, III et al. reference and what teaching in the reference that the Examiner is relying on to meet these limitations. The Examiner is requested to communicate the portions of the reference being relied upon. This is a clear structural difference between the cited art and Applicant's claim. This argument was presented by Applicant in the response filed July 7, 2003 following the First Office Action and in the response of November 21, 2003 but has not been addressed by the Examiner.

Because the Osborn, III et al. reference is deficient for the reasons advanced above, the Osborn, III et al. reference fails to make obvious the limitations of claim 23. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 24:**

The rejection of claim 24 should be withdrawn because the Osborn, III et al. reference does not recite a removable closure cap, as claimed by Applicant. In fact, there is no motivation, nor would there be a reason to provide, a removable closure cap. The tampon-dispensing device of Osborn, III et al. is designed to maintain a sealed gas inside the device. The design and structure of the Osborn, III et al. tampon dispenser does not lend itself to inclusion of a removable closure cap. A removable closure cap, as recited in Applicant's claim 24, used in Osborn's tampon dispensing device would release the sealed gas if removed. The purpose of the removable closure cap in Applicant's claimed invention is for mating with and closing the forward end opening of the syringe so as to maintain sterility of the inner walls of the syringe barrel and to retain materials in the syringe barrel. It is unclear how the Osborn, III et al. reference meets the limitations of claim 24. The Osborn, III et al. reference does not teach the limitations of claim 24. This argument was presented by Applicant in the response of

July 7, 2003 following the First Office Action and in the response of November 21, 2003, but has not been addressed by the Examiner. The Examiner is requested to communicate the portions of the reference being relied upon.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Osborn, III et al. reference does not recite a brace means, as claimed by Applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not inadvertently expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. This is a clear structural difference between Applicant's claimed subject matter and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet the limitation. The Examiner is requested to communicate the portions of the reference being relied upon. The Osborn, III et al. reference does not teach the limitations of claim 26. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action and in the response of November 21, 2003, but has not been addressed by the Examiner.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 27:**

The rejection of claim 27 should be withdrawn because the Osborn, III et al. reference does not recite or show a syringe (the device of Osborn III, et al. is a tampon dispenser and not a syringe) having a forward end that tapers to a reduced diameter neck, where the reduced diameter neck forms a permanent forward end opening, as claimed by Applicant. These structural limitations of the instant invention provide an entrance/exit port for flowable materials to be drawn into and expelled or ejected from the syringe barrel. The Osborn, III et al. reference does not teach a syringe having a

reduced diameter neck that forms a permanent forward end opening as required by the claim. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet the limitations. The Examiner is requested to communicate the portions of the reference being relied upon. The Osborn, III et al. reference does not teach the limitations of claim 27. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 29:*

The rejection of claim 29 should be withdrawn because the Osborn, III et al. reference does not recite or show a syringe (the device of Osborn III, et al. is a tampon dispenser and not a syringe) having a corrugated sheath which does not automatically recoil after being lengthened or compressed. The Osborn, III et al. reference is silent regarding this limitation and it cannot be assumed to be present in bellows 100.

It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference that the Examiner is relying on to meet this limitation. The Examiner is requested to communicate the portions of the reference being relied upon. The Osborn, III et al. reference does not teach the limitations of claim 29. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn, III et al. and the Examiner is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 30:*

The rejection of claim 30 should be withdrawn because the Osborn, III et al. reference does not recite a corrugated sheath enclosing the length of the plunger existing between the rearward end face surface of said syringe barrel handle member and the forward face of the plunger handle member, as claimed by Applicant. Regarding the attachment of the corrugated sheath to the rear face surface of the syringe barrel handle member, the Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 and not to gripping means 60. Note that the limitations of Applicant's claim 1, from which claim 30 depends, require that the corrugated sheath be attached to the rearward end face surface of said syringe barrel

handle member; the handle member is, in turn, permanently attached to the rearward end terminus of the syringe barrel. Applicant's claim 1 also requires attachment of corrugated sheath to the forward face surface of the plunger shaft handle member. Regarding attachment of the bellows 100 to the gripping means 70, the Osborn, III et al. reference does not recite or show that the bellows 100 is molded to the gripping means 70, such that the bellows 100 encloses the length of the plunger existing between the forward face of gripping means 70 and the rearward end face surface of gripping means 60, as claimed by Applicant. The Osborn, III et al. reference is silent and makes no attempt to discuss an attachment relationship between the bellows 100 and the gripping means 70, or even if an attachment is present. One cannot absolutely conclude from the drawings if attachment exists between bellows 100 and gripping means 70 or between the bellows 100 and the plunger 30. To meet the limitation of claim 30, Osborn, III et al. must recite attachment between the forward face surface of gripping means 70 to the bellows 100. The reference must recite the claimed limitation – it cannot be assumed to be present. Accordingly, it cannot be determined precisely what section of the plunger shaft the bellows 100 is enclosing in Osborn, III et al. because the attachment of the forward end of bellows 100 is to the cylinder 50 and the point of attachment of the rearward end of bellows 100 is undisclosed and cannot be determined. The Osborn, III et al. reference certainly does not meet the limitations of claim 30. These are clear and patentable structural distinctions between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet the limitations. The Osborn, III et al. reference does not teach the limitations of claim 30. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn, III et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 31:**

The rejection of claim 31 should be withdrawn because the Osborn, III et al. reference does not teach a rearward end opening for entrance and exit of the plunger shaft; specifically, withdrawal of the plunger 30 from cylinder 50. Withdrawal of the plunger shaft in the Osborn, III et al. reference, if at all possible, would leave the tampon spaced apart from the plunger 30. The intent and purpose of the Osborn, III et al. reference is to dispense the tampon 20 by pushing plunger 30 towards gripping

means 60. In fact, the reference does not disclose that withdrawal of the plunger 30 is possible and does not recite anywhere in the reference that withdrawal of the plunger 30 is performed or even feasible – it certainly is not warranted in order to dispense tampons. It is also noted that the bellows 100 plays a role in whether the plunger can even be withdrawn. A bellows 100 that is fully extended or elongated will not allow further withdrawal, only advancement – which is the operation Osborn, III et al. intends the tampon dispenser to perform. Note that the Osborn, III et al. reference never teaches or suggests withdrawal of the plunger 30. The tampon dispenser of Osborn, III et al. and the syringe of Applicant's invention are different, do not have the same connectivity, function differently, and are for different purposes. A person desiring a syringe to perform a function such as drawing or ejecting fluids as disclosed by Applicant would not consider a tampon dispenser having a tampon therein to perform the desired function.

The reference must recite the claimed limitation – it cannot be assumed that the plunger 30 of the tampon-dispensing device can be withdrawn from the cylinder 50. It certainly should not be assumed where there is no motivation or rationale for performing the function. Thus, the structure relied upon by the Examiner is not capable of performing the claimed function. These are clear and patentable structural and functional distinctions between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference that the Examiner is relying on to meet these limitations. The Osborn, III et al. reference does not teach the limitations of claim 31. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 32:*

The rejection of claim 32 should be withdrawn because the Osborn, III et al. reference does not recite, disclose, or require the use of an attached piston. Accordingly, the plunger 30 of Osborn, III et al. does not extend between an attached piston and a plunger handle member. The Examiner indicated in the interview of November 6, 2003, with regard to claim 1, that the tapered portion of the plunger 30 was being relied upon as meeting the limitation of an attached piston. Applicant presented the argument that the tapered portion of the plunger 30 is not an attached

piston. Applicant repeated this position in the response of November 21, 2003 indicating that the tapered portion of the plunger 30 of the Osborn, III et al. reference is not a piston, but is actually the plunger 30. The plunger shaft and piston claimed by Applicant are different parts, which are attached together. The tapered portion of plunger 30 in the Osborn, III et al. reference is not attached to the plunger 30, *but is plunger 30*. The term "attached" has meaning. This is a clear structural difference between the Osborn, III et al. reference and Applicant's claim. Further, the tapered portion of the plunger 30 taught by Osborn, III et al. is not capable of functioning as a piston in a syringe, as claimed by Applicant and taught by Applicant's specification. Also, the attached piston must be capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity and along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston, as presented in claim 1 – from which claim 32 depends. The tampon dispenser of Osborn, III et al. is not capable of performing this function. There are major structural differences between Applicant's claimed syringe and the tampon dispenser of Osborn, III et al. Accordingly, the Osborn, III et al. reference does not teach that the plunger shaft is a single and continuous component extending between a piston and a plunger shaft handle member. This is a clear and patentable structural difference between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the Osborn, III et al. reference meets the claimed limitations. The Osborn, III et al. reference does not teach the limitations of claim 32. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

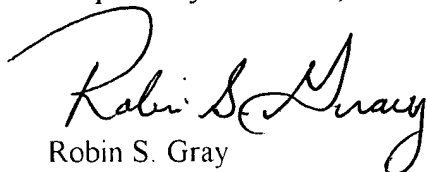
Conclusion

The Applicant is unclear where the Examiner stands on many of the issues raised by Applicant in the response of July 7, 2003 following the First Office Action, because the Examiner has not responded to the all arguments presented in that response. Applicant argued in the July 7, 2003 response that many of the limitations of the dependant claims were not addressed by the First Office Action or were clearly inaccurate. Applicant also presented amended claims and new claims in that response. The Examiner has continued to reject the claims and not respond to each of the arguments presented by Applicant. The Examiner's subsequent response of September 10, 2003 to Applicant's arguments did not address Applicant's concerns regarding the Examiner's First Office Action. Further, Applicant does not understand the basis of the rejections for the

independent claim and the dependant claims. The rejections in the First Office Action and subsequent Final Office Actions fail to address all of the claim limitations of the independent and dependant claims. The Applicant has continued to request clarification of these issues throughout prosecution, but the Examiner has not responded to these requests. The Examiner has not explained in the rejections or in responses to Applicant's arguments, how the rejections meet the claim limitations. The Examiner should communicate the portions of the references being relied upon. Applicant believes that the art does not anticipate or make obvious the limitations of the claimed subject matter and that the rejections should be withdrawn.

Applicant respectfully submits that the above arguments place the application for patent in condition for allowance and early notification to that effect is respectfully requested.

Respectfully submitted,



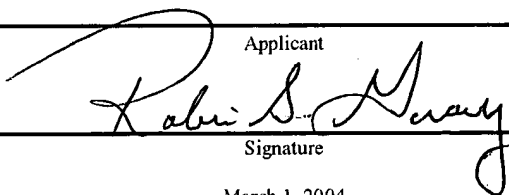
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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450, on March 1, 2004.

Robin S. Gray

Applicant



Signature

March 1, 2004

Date of Signature